

5

Docket No. G-091US05DIV
Serial No. 09/992,095Remarks

Claims 14-52 are pending in the subject application. Applicants acknowledge that claims 14-29 and 37-52 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have amended claims 30, 31, 34, and 36, canceled claims 14-29, 32, 33, 35, and 37-52, and added new claims 53-59. Support for the amendments and new claim can be found throughout the subject specification and in the claims as originally filed (see, for example, page 202, lines 2-10 and the original claims). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 30, 31, 34, 36, and 53-59 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

By way of the Amendment of this date, Applicants have submitted method of use claims related to the plasminogen polypeptide. Applicants acknowledge that the Patent Office may, where appropriate, require applicant, under 35 U.S.C. § 121, to elect claims to either the product or process and that claims directed to the non-elected invention are withdrawn from further consideration under 37 C.F.R. § 1.142. However, Patent Office policy related to the treatment of product and process claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b) indicates that if applicant elects claims directed to the product and the product is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product will be rejoined. With respect to this policy, Applicants respectfully submit that claims 55-59 relate to withdrawn process claims that include all the limitations of, or depend from, the product claims under examination in this matter. Should the product claims currently under examination in this matter be found allowable by the Patent Office, Applicants respectfully request that the Patent Office rejoin claims 55-59 with the currently pending claims and that these claims be allowed as well.

The "Related Applications" section of the subject application is objected to on the grounds the specification fails to claim priority to U.S. application Serial Nos. 60/298,698 and 60/293,574. In addition, the specification is objected to because it does not indicate that the subject application is a divisional of parent application Serial No. 09/924,340. Applicants respectfully assert that the "Related Applications" section of the subject application was amended to correct such issues in their Election Under 35 U.S.C. § 121 dated July 28, 2004 (see page 2 of the amendment/election).

J:\GEN091.US05.DIV\Amend-Resp\Amd.doc/DNB/sl

The specification is also objected to because the subject specification (at page 200, lines 30-32) states that plasminute consists of residues 585-790 of plasminogen but SEQ ID NO: 2 consists of residues 585-791 of the plasminogen sequence. Applicants gratefully acknowledge the Examiner's careful review of the subject specification. By this Amendment, Applicants have amended the specification to indicate that the plasminute consists of residues 585-791. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

The specification is also objected to because it fails to define the term "GENSET." Applicants respectfully submit that the term relates to the various polypeptides and polynucleotides disclosed within the specification and that definition of the term is not required.

The Examiner has indicated that the title of the invention is not descriptive. Applicants have amended the title of the invention to "Plasmin Variants and Uses Thereof." Accordingly, reconsideration and withdrawal of this objection is respectfully requested.

The Examiner asserts that the oath or declaration submitted in the subject application is defective on the grounds that the filing date for U.S. application Serial No. 60/293,574 is incorrectly listed. Applicants note that an Application Data Sheet was submitted to the Patent Office when the subject application was filed which correctly listed the filing date for U.S. application Serial No. 60/293,574 as May 25, 2001. Therefore, Applicants do not believe it is necessary to provide a newly executed Declaration in view of 37 C.F.R. 1.76(d)(2) which indicates that the Application Data Sheet will govern when the inconsistent information is supplied at the same time by an amendment to the specification, a designation of correspondence address, or a § 1.63 or § 1.67 oath or declaration, except as provided by paragraph (d)(3) of this section. However, if the Examiner maintains this objection in the next Action, Applicants will endeavor to obtain a newly executed Declaration by the inventors. Accordingly, reconsideration and withdrawal of this objection is respectfully requested.

The abstract is objected to because the term "GENSET" should be defined and the word "and" should be inserted. As the Abstract has been amended to reflect the currently claimed invention, it is respectfully submitted that this issue is moot. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

The Information Disclosure Statement dated April 26, 2002 is objected to for failing to state the database in which the disclosed sequences for Accession No. AAR34428 and Accession No.

JAGI:M091.US05.DIVAmend-Resp\Amd.doc/DNB/sl

AAR56472, identified as "ab" and "ac", respectively, can be found and that a new "US PTO/1449" is required. Submitted with this Amendment is a new Form PTO/SB/08 (substituted for Form PTO-1449) which provides a complete reference for Accession No. AAR34428 and Accession No. AAR56472. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claim 30 is objected to for being dependent upon a non-elected claim. Applicants have amended claim 30 to include the limitation of canceled claim 29. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claim 32 is rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants respectfully assert that the claims as filed are definite. However, by this Amendment, claim 32 has been canceled, thereby rendering this rejection moot. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 31-33 and 36 are rejected under 35 U.S.C. § 112, first paragraph, as nonenabled by the subject specification and as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully assert that the claims are enabled by the subject specification and that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention. Applicants note that claims 32 and 33 have been canceled, thereby rendering the rejections of those claims moot. The Office Action indicates that the specification is enabled for the polypeptide of SEQ ID NO: 54 but does not provide enablement for any fragment of SEQ ID NO: 54. Applicants note that claim 31 has been amended to delete reference to "or a polypeptide fragment thereof" and that the claim is now directed to a protease rather than a polypeptide. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claim 30 is rejected under 35 U.S.C. § 102(b) as anticipated by Petersen *et al.* (1990) or Castellino *et al.* (1995). In addition, claims 31-36 are rejected under 35 U.S.C. § 102(c) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Aguzzi *et al.* (2002). The Office Action indicates that the Petersen *et al.* and Castellino *et al.* references teach a polypeptide, human plasminogen, comprising SEQ ID NO: 54. The Office Action further states that

J:\GEN091.US05.DIV\Amend-Resp\Amd.doc\DNB/sl

the Aguzzi *et al.* references teaches peptide libraries of human plasminogen fragments linked to beads, displayed on phage, or expressed in host cells. Applicants respectfully traverse.

Applicants respectfully submit that the Petersen *et al.* and Castellino *et al.* references do not teach a variant consisting of the 207 carboxy-terminal amino acids of human plasminogen. Applicants also point out that plasminute corresponds to variant of human plasminogen. Specifically, amino acids 1 to 207 of plasminute are identical to amino acids 604 to 810 of plasminogen. The subject application relates to factors that selectively interact with an infectious isoform of the prion, but not with a normal, non-infection isoform of the prion. The factor may correspond to a fragment of human plasminogen. Applicants respectfully assert that the Aguzzi *et al.* reference does not teach a fragment consisting of the 207 carboxy-terminal amino acids of human plasminogen. In addition, Applicants submit that numerous fragments can be generated from an 810 amino acids long protein. The Aguzzi *et al.* reference does not suggest to generate a plasminogen fragment consisting of the 207 carboxy-terminal amino acids of human plasminogen. Accordingly, reconsideration and withdrawal of the rejections is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

9

Docket No. G-091US05DIV
Serial No. 09/992,095

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCI/sl

Attachment: Form PTO/SB/08 (1 page)

J:\GEN\091.US05.DIV\Amend-Resp\Amend.doc/DNB/sl